

REMARKS/ARGUMENTS

Claims 1-12 and 19-20 are active. Claims 13-18 have been withdrawn from consideration. A clean set of claims is presented as a convenience to the Examiner, however, no amendments have been made and no new matter introduced. Favorable consideration of this amendment and allowance of the application is respectfully requested.

Request for Withdrawal of Final Rejection

A new rejection under 35 U.S.C. 112, second paragraph, was imposed for using the word "block copolymerization". This term appears in the original claims and in the previous version of Claim 11, therefore this rejection was not necessitated by amendment and the finality of the last Official Action should be withdrawn.

Restriction/Election

Applicants previously elected with traverse, Group I, Claims 1-12, directed to a pH-sensitive polymer and a method of making it. Claims 13-18, directed to medicinal substances containing the pH-sensitive polymer, have been withdrawn from consideration. The Restriction Requirement has now been made FINAL.

The Applicants respectfully request that the claims of the nonelected group which depend from or include all the limitations of those of elected Group I, be rejoined upon an indication of allowability for the elected claims, see MPEP 821.04.

Rejection—35 U.S.C. §112, first paragraph

Claim 1 was rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for a negative limitation. The specification (Table 1 on page 25 of the specification) describes pH-sensitive polymers which do not contain transition metal

complexes and thus provides descriptive support for this limitation. Exemplification of this subject matter shows that the Applicants possessed the invention. Possession may be shown in a variety of ways and literal *in haec verba* (“in these words”) description of a claim limitation is not required, MPEP 2163.02; *In re Anderson*, 176 USPQ 331 (CCPA 1973):

In determining whether amendment to claim constituted new matter, question is not whether added word was a word used in specification as filed but whether there is support in specification for employment of word in claim, i.e., whether concept is present in original disclosure.

Here, the concept of pH-sensitive polymers without transition metal content is present in the original disclosure and is actually exemplified. Accordingly, the Applicants respectfully ask that this rejection be withdrawn.

Rejection—35 U.S.C. §112, second paragraph

Claims 11 and 19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for using the term “block polymerization”. This term is described on page 14, line 21 of the specification. Block polymerization is a well-known form of copolymerization. A block copolymer is formed when the polymerization reaction is carried out in a stepwise manner, leading to a structure with long sequences or blocks of one monomer alternating with long sequences of the other, see entry for “Polymer” in Wikipedia (<http://en.wikipedia.org/wiki/Polymer>).

Rejection—35 U.S.C. §103

Claims 1-12 and 19-20 were rejected under 35 U.S.C. 103(a) as being obvious over, Haddleton et al., U.S. Patent 5,804,632, in view of Rehmer et al., U.S. Patent No. 6,225,401. The Applicants respectfully traverse this rejection, because neither cited document suggests omitting transition metal complexes, suggest producing a pH-sensitive polymer with the biological properties required by Claim 1, nor does either document provide a reasonable

expectation of success for a pH-sensitive polymer having these properties by omitting transition metal complexes. Neither Haddleton nor Rehmer even contemplates a pH-sensitive polymer with these properties and therefore the cited prior art cannot suggest or provide a reasonable expectation of success for the functionally-limited subgenus of pH-sensitive polymers of the invention.

No suggestion to omit metals. The Haddleton polymer may be used for various applications, particularly “binder material in coating applications” (col. 1, lines 11-12). There is no suggestion in Haddleton to specifically select polymers not containing biologically toxic components and these polymers contain toxic transition metal ions, such as cobalt, which remain from a catalytic chain transfer (CCT) polymerization which requires the presence of these toxic metals, see Haddleton, col. 1, lines 50-52 and col. 3, lines 34-40. These remaining transition metals are toxic and thus would not bring about less than 5% hemolysis at pH 7.4 as required by Claim 1, because they would kill cells exposed to them. Haddleton does not anticipate the present invention or render it obvious, since there is no disclosure or suggestion of polymers not containing toxic transition metals, nor of complexes which bring about less than 5% hemolysis at pH 7.4.

Rehmer is directed to production of concentrated adhesive dispersions (see Title, Abstract, and Claims) and was cited as disclosing the addition of regulators to a polymerization mixture to reduce the degree of polymerization. However, Rehmer does not complement the primary reference, since it does not suggest omitting transition metal from the polymerization process. In fact, col. 3, line 23, refers to a process taking place in the presence of “polyvalent metal ions” such as iron or vanadium.

No suggestion to select polymers having the functional properties required by Claim 1. Neither document discloses an application requiring a pH-sensitive polymers having the

biological properties required by Claim 1. Therefore, the prior art even in combination provides no motivation for selecting the polymers of the invention.

Not an inherent property. Must be selected. The biological properties of the pH-sensitive polymers of the invention are not inherent to polymer mixtures of methacrylic and (meth)acrylic acid units. This is evident from Polymer S-100 (see Tables 1 and 2, pages 25 and 27 of the specification) which falls within the composition ranges of Claim 1, but does not inherently have the required biological properties. The prior art does not inherently disclose nor suggest selection of pH-sensitive polymers having the functional properties of those of the invention.

Accordingly, since the prior art does not suggest omitting toxic metals and does not suggest selecting a subgenus of products having the required biological properties, nor provide any reasonable expectation of making such, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. An early notification to that effect is earnestly solicited.

Respectfully submitted,

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